And fizer enters the running for best made up last minute document for VRBPAC race!

This article focuses on the 6-23 month year olds.

Jessica Rose
Jun 13

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"All adverse events were considered related to the vaccine by the study investigator and FDA."

Wait now. Isn't that causation? I thought that couldn't happen with vaccines and experimental injectable products. To the people on the narrative fence, say it with me now:

I GUESS I WAS WRONG. It's ok to be wrong and admit it. It's not ok to keep telling stories that result in injury. There's a word for that.

Ok. Please head to this fantastic new document released 2 days before the VRBPAC meeting. Read this quote from page 13 to get some context. You know, how many infants they injected, how they pretended to do adequate immunogenicity study using 'immunobridging' and how they only had serological data from 146 BNT162b2 recipients and 73 placebo recipients. Just as a start.

Just so you know, they determined the efficacy of this dose of Pfizer products in infants by measuring and comparing the concentration of neutralizing antibodies against a 'randomly selected subset' of ***16-25-year-old participants***. I'm sorry, but that's absolute sheit. You can read Toby's Substack to find out how and why in a more detailed way.

> Participants 6-23 months of age: Safety data from 1,178 BNT162b2 (3 µg) recipients and 598 placebo recipients, of whom 461 (60.8%) and 68 (37.0%), respectively, had at least 2 months (blinded and open-label) safety follow-up after completing a three-dose primary series. Vaccine effectiveness was inferred by immunobridging based on a comparison of immunogenicity endpoints (SARS-CoV-2 neutralizing antibody geometric mean concentrations (GMTs) and seroresponse rates 1 month after Dose 3) between participants 6-23 months of age from study C4591007 (n=146) and participants 16 through 25 years of age from study C4591001. Efficacy against COVID-19 was also assessed descriptively.

So they had 1,178 infants in the drug arm (3 ug) and 598 in the placebo arm. The placebo arm participants were monitored for 2 months. Then apparently, most of the remainder of the placebo participants (58%) were injected with the drug following unblinding. I guess this again, was due to the fact that it was 'unethical' to refuse these babies the joy of being injected with an experimental product during a clinical trial?

When you destroy the control group, you destroy the study. It is not a Randomized Controlled Trial (RCT), in this case. The 'gold standard' is for fools. (See the cleverness there in that word-smithing?) It's in the name. That's what the 'C' stands for, see?

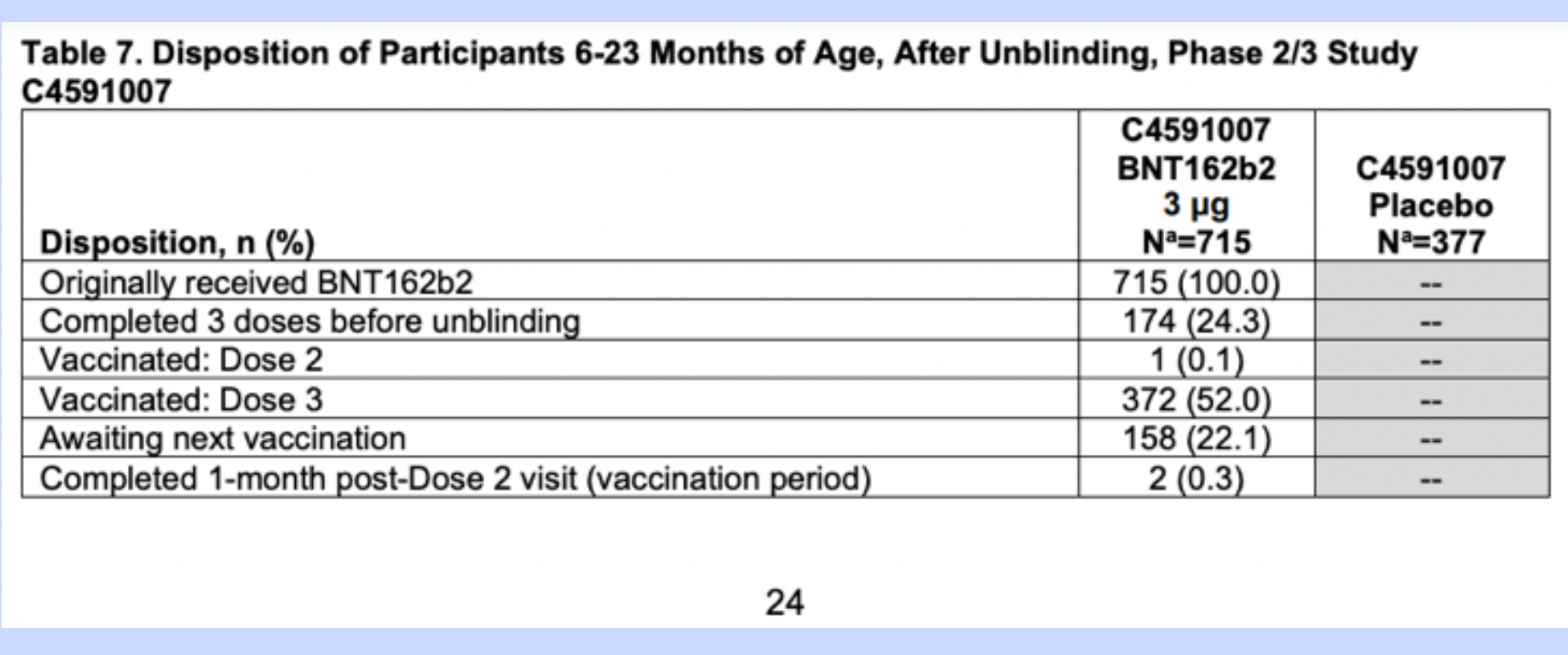

Table 7. Disposition of Participants 6-23 Months of Age, After Unblinding, Phase 2/3 Study C4591007

Disposition, n (%)	C4591007 BNT162b2 3 µg N^a=715	C4591007 Placebo N^a=377
Originally received BNT162b2	715 (100.0)	--
Completed 3 doses before unblinding	174 (24.3)	--
Vaccinated: Dose 2	1 (0.1)	--
Vaccinated: Dose 3	372 (52.0)	--
Awaiting next vaccination	158 (22.1)	--
Completed 1-month post-Dose 2 visit (vaccination period)	2 (0.3)	--

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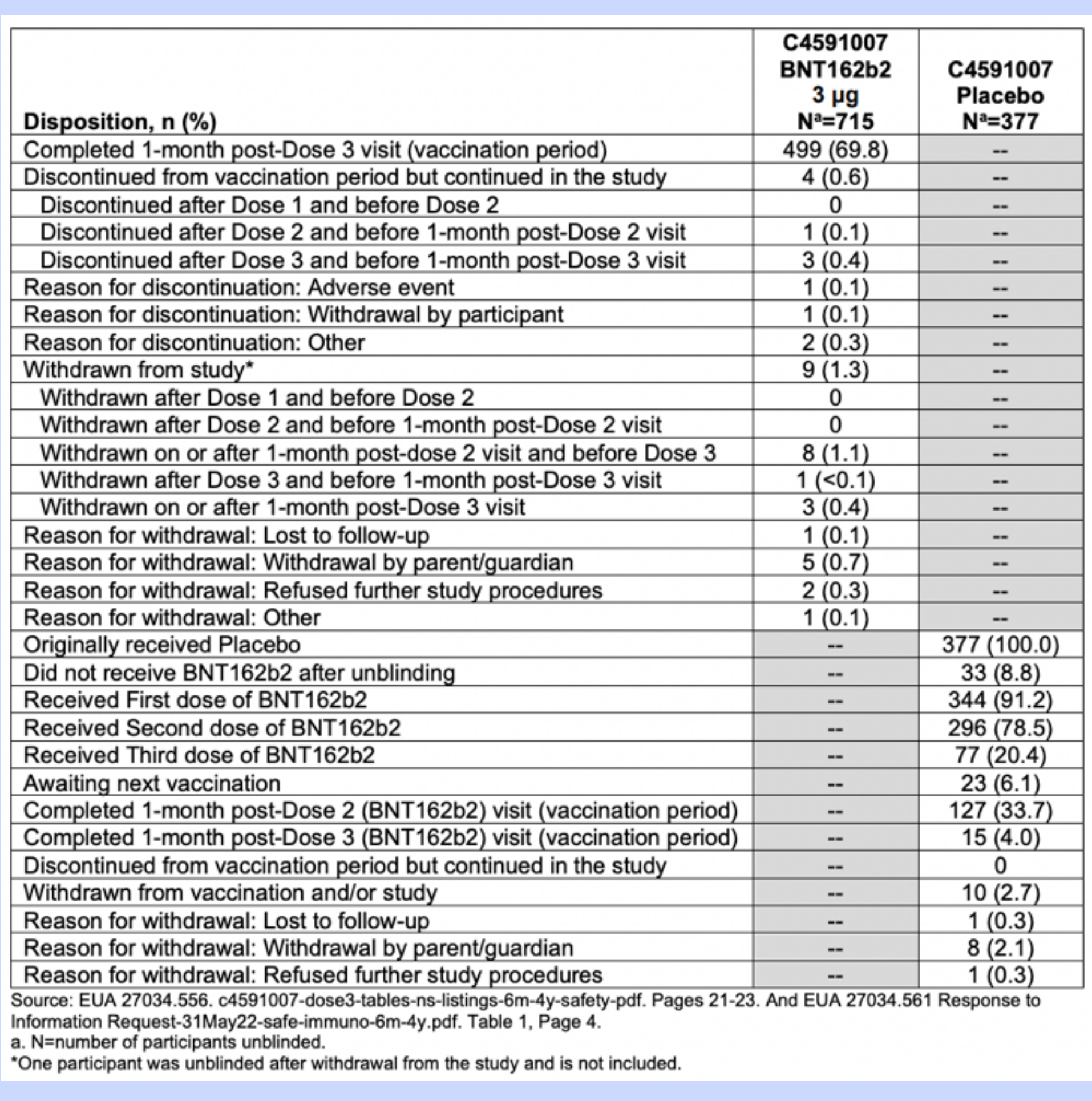

Disposition, n (%)	C4591007 BNT162b2 3 µg N^a=715	C4591007 Placebo N^a=377
Completed 1-month post-Dose 3 visit (vaccination period)	499 (69.8)	--
Discontinued from vaccination period but continued in the study	4 (0.6)	--
Discontinued after Dose 1 and before Dose 2	0	--
Discontinued after Dose 2 and before 1-month post-Dose 2 visit	1 (0.1)	--
Discontinued after Dose 3 and before 1-month post-Dose 3 visit	3 (0.4)	--
Reason for discontinuation: Adverse event	1 (0.1)	--
Reason for discontinuation: Withdrawal by participant	1 (0.1)	--
Reason for discontinuation: Other	2 (0.3)	--
Withdrawn from study*	9 (1.3)	--
Withdrawn after Dose 1 and before Dose 2	0	--
Withdrawn after Dose 2 and before 1-month post-Dose 2 visit	0	--
Withdrawn on or after 1-month post-dose 2 visit and before Dose 3	8 (1.1)	--
Withdrawn after Dose 3 and before 1-month post-Dose 3 visit	1 (<0.1)	--
Withdrawn on or after 1-month post-Dose 3 visit	3 (0.4)	--
Reason for withdrawal: Lost to follow-up	1 (0.1)	--
Reason for withdrawal: Withdrawal by parent/guardian	5 (0.7)	--
Reason for withdrawal: Refused further study procedures	2 (0.3)	--
Reason for withdrawal: Other	1 (0.1)	--
Originally received Placebo	--	377 (100.0)
Did not receive BNT162b2 after unblinding	--	33 (8.8)
Received First dose of BNT162b2	--	344 (91.2)
Received Second dose of BNT162b2	--	296 (78.5)
Received Third dose of BNT162b2	--	77 (20.4)
Awaiting next vaccination	--	23 (6.1)
Completed 1-month post-Dose 2 (BNT162b2) visit (vaccination period)	--	127 (33.7)
Completed 1-month post-Dose 3 (BNT162b2) visit (vaccination period)	--	15 (4.0)
Discontinued from vaccination period but continued in the study	--	0
Withdrawn from vaccination and/or study	--	10 (2.7)
Reason for withdrawal: Lost to follow-up	--	1 (0.3)
Reason for withdrawal: Withdrawal by parent/guardian	--	8 (2.1)
Reason for withdrawal: Refused further study procedures	--	1 (0.3)

Source: EUA 27034.556. c4591007-dose3-tables-ns-listings-6m-4y-safety-pdf. Pages 21-23. And EUA 27034.561 Response to Information Request-31May22-safe-immuno-6m-4y.pdf. Table 1, Page 4.
a. N=number of participants unblinded.
*One participant was unblinded after withdrawal from the study and is not included.

https://www.fda.gov/media/159195/download. Page 24 and 25.

"A total of 13 participants withdrew from the study (9 BNT162b2 recipients and 4 placebo recipients)." Ok.

"Participants 6-23 months of age Among participants 6-23 months of age, 3 BNT162b2 recipients and no placebo recipients withdrew from the study due to an AE. One BNT162b2 recipient developed fever (>40°C) 2 days post-Dose 1 that resolved in 3 days, with concurrent exanthema subitem (viral infection) that resolved in 4 days. Another BNT162b2 recipient with a history of eczema developed a generalized rash 5 days after receiving Dose 1, which resolved by Day 9. Additionally, 1 BNT162b2 recipient reported pyrexia 3 days post Dose 3 that resolved in 3 days." Hmm. Ok. Exanthema subitem! Nice words. Makes me feel stupid. How about you?

> 6.3. Known and potential risks
>
> In study participants 6 months through 4 years of age, there were numerically higher rates of solicited local and systemic ARs in BNT162b2 recipients than in placebo recipients.

Really? That's surprising.

> One 6-month-old BNT162b2 recipient was reported to have an SAE of seizure (eye rolling upwards) that occurred 2 days after Dose 2, preceded by symptoms of a respiratory tract infection and temperature of 38.0°C. The participant was evaluated in the emergency department and admitted to the hospital for evaluation of seizure: with eye rolling upwards noted once on an otherwise normal physical/neurological examination.

Watch this movie and this movie for a specific story of what happened to a young infant that suffered this same AE following injection.

> Convulsions were reported at a similar incidence in the BNT162b2 (n=4, 0.3%) and placebo (n=1, 0.2%) groups. These included: 2 events of seizure in the BNT162b2 group, one of which occurred 3 days post-Dose 2 and was reported as an SAE (Section 4.2.7.5), and the other was a nonserious event with onset 164 days post-Dose 2; and 2 events of febrile convulsion in the BNT162b2 group, one of which was reported as an SAE (Section 4.2.7.5), and both of which occurred >30 days after vaccination. All were considered by the study investigator and by FDA as not related to study intervention.

Convulsions. Seizures. Wow. That sounds pretty bad considering we're talking about infants so young they have barely 'learned' to hold their own heads up.

> Participants 6-23 months of age Among participants 6-23 months of age, SAEs were reported in 17 (3.1%) participants in the BNT162b2 group and 14 (2.3%) in the placebo group, most of which were gastrointestinal or respiratory illnesses/infections that occur commonly in this age group. SAEs reported in the BNT162b2 group included RSV bronchiolitis (5 participants), pneumonia (2 participants), gastroenteritis (2 participants), lower respiratory tract infection (2 participants), and the following events were each reported once (a participant can report more than one event): anal abscess, anaphylaxis, lower respiratory tract infection, viral lower respiratory tract infection, metapneumovirus infection, rhinovirus infection, rotavirus gastroenteritis, viral gastroenteritis, accidental overdose, febrile convulsion, seizure. None of the SAEs in the BNT162b2 group were considered by the study investigator or by FDA to be related to vaccination, given the time to onset after vaccination and/or plausible alternate etiology.

Gastrointestinal eh? Isn't that how they described Maddie de Garay's AEs?

I have so many more screenshots to show you but there's no need. Enough. The data is sparse, lamentable, has a terribly useless efficacy assessment, terrible safety profile… What more do we need?

I mean, look at the rates in the red box. 61% of the infants experienced and reported a reaction within 7 days following Dose 1? Really? And how the hell is that 58.2% of the infants injected with placebo experienced a reaction as well? Are we talking about 'injection site redness' or something more serious? Because, last time I checked, 'systemic' meant 'everywhere'. Right? It seems that no, they checked the 'injection site reaction' and those rates were about half the systemic rates. And what of the SAE (Severe Adverse Events) rates? I am sorry but I have to ask because it does not make sense to me. Why and how would 2.3/100 (or 1/43) infants on the placebo experience an SAE? Huh?

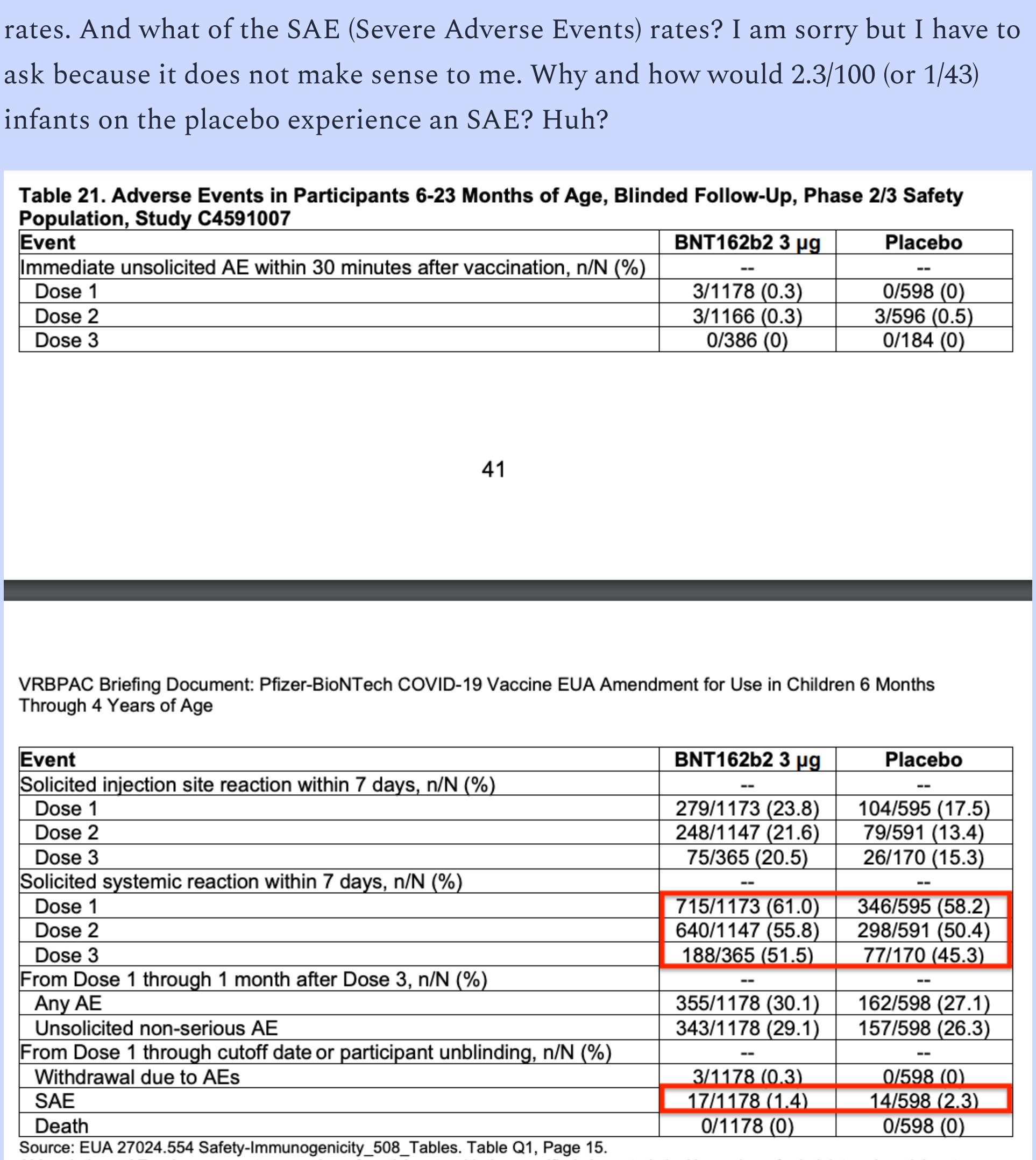

Table 21. Adverse Events in Participants 6-23 Months of Age, Blinded Follow-Up, Phase 2/3 Safety Population, Study C4591007

Event	BNT162b2 3 µg	Placebo
Immediate unsolicited AE within 30 minutes after vaccination, n/N (%)	--	--
Dose 1	3/1178 (0.3)	0/598 (0)
Dose 2	3/1166 (0.3)	3/596 (0.5)
Dose 3	0/386 (0)	0/184 (0)

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VRBPAC Briefing Document: Pfizer-BioNTech COVID-19 Vaccine EUA Amendment for Use in Children 6 Months Through 4 Years of Age

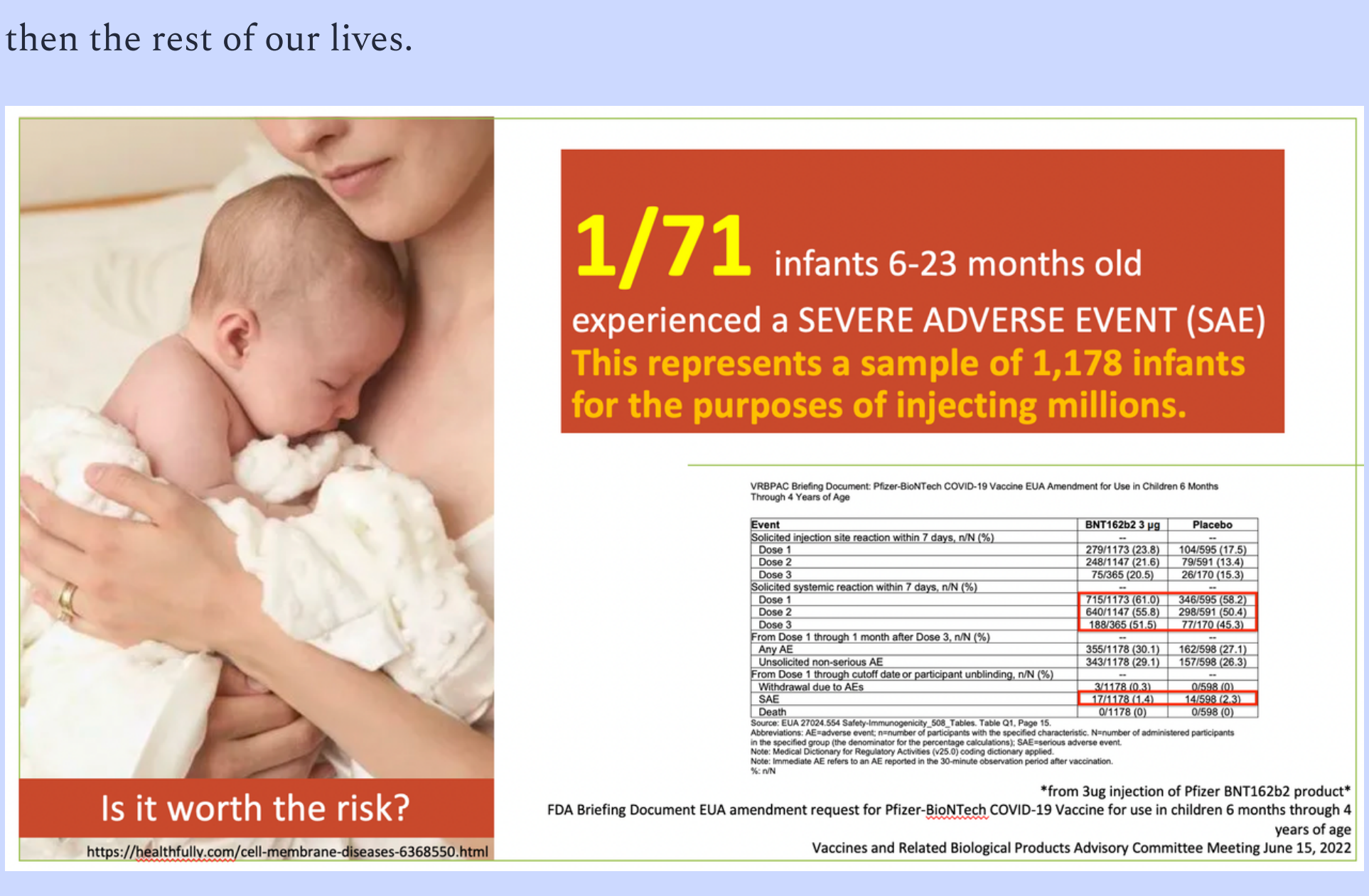
Event	BNT162b2 3 µg	Placebo
Solicited injection site reaction within 7 days, n/N (%)	--	--
Dose 1	279/1173 (23.8)	104/595 (17.5)
Dose 2	248/1147 (21.6)	79/591 (13.4)
Dose 3	75/365 (20.5)	26/170 (15.3)
Solicited systemic reaction within 7 days, n/N (%)	--	--
Dose 1	715/1173 (61.0)	346/595 (58.2)
Dose 2	640/1147 (55.8)	298/591 (50.4)
Dose 3	188/365 (51.5)	77/170 (45.3)
From Dose 1 through 1 month after Dose 3, n/N (%)	--	--
Any AE	355/1178 (30.1)	162/598 (27.1)
Unsolicited non-serious AE	343/1178 (29.1)	157/598 (26.3)
From Dose 1 through cutoff date or participant unblinding, n/N (%)	--	--
Withdrawal due to AEs	3/1178 (0.3)	0/598 (0)
SAE	17/1178 (1.4)	14/598 (2.3)
Death	0/1178 (0)	0/598 (0)

Source: EUA 27024.554 Safety-Immunogenicity_508_Tables. Table Q1, Page 15.
Abbreviations: AE=adverse event; n=number of participants with the specified characteristic. N=number of administered participants in the specified group (the denominator for the percentage calculations); SAE=serious adverse event.
Note: Medical Dictionary for Regulatory Activities (v25.0) coding dictionary applied.
Note: Immediate AE refers to an AE reported in the 30-minute observation period after vaccination.
%: n/N

https://www.fda.gov/media/159195/download. Page 41 and 42.

And even if we forget we saw that and focused on the SAE rate for the BNT162b2 3 ug arm, 1.4/100 (1/71) infants suffered a SEVERE ADVERSE EVENT? WHAT IN THE HOLY HELL? Oh and don't forget, they only checked 1,178 infants. For the purposes of injecting millions.

Here's a similar poster for you to print and distribute. We have one day left. And then the rest of our lives.



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Igor Chudov Writes Igor's Newsletter Jun 13

You are my hero Jessica

69 Reply Collapse

3 replies

Hubris Jun 13 · *edited Jun 13*

From Toby's Substack:

"What is to be done

Children's Health Defense just launched an excellent 1-click call to action that I highly encourage you to do (and please share it with all of your friends).

Up until Monday night (June 13) at 11:59 p.m. eastern time you can officially register your profound displeasure with the FDA by submitting a formal comment (here) — look for the blue Comment button in the upper left corner of the website. 129,397 comments have already been received — let's see if we can get that number above 140,000. "

https://childrenshealthdefense.org/child-health-topics/take-action/urgent-send-your-lawmakers-rfk-jr-s-letter-to-fda-vrbpac-committee-members/

I did that yesterday - found out about it from the CHD website... what are YOU waiting for?

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Jessica Rose PhD, MSc, BSc and Peter A. McCullough MD, MPH
JESSICA ROSE NOV 2, 2021 1,192 141

Rewrite: Let's tag team this until everybody understands
The modified spike protein is dangerous and for very specific reasons.
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When you hear BNT162c(2), run, don't walk, RUN away.
It's already in the clinical 'trials'
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